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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Shinichi Watanabe

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EXAMINER

TON, THAIAN N

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,570	<b>Applicant(s)</b> WATANABE ET AL.	
	<b>Examiner</b> Thaian N. Ton	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-13, 16-23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6-8, 10-13, 16-23, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/20/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/20/05</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants Amendment and Remarks, filed 7/24/09, have been entered. Claims 14 and 15 are cancelled; claims 1, 2, 10, 16-18, 22, 23, 25 and 26 are amended; claims 1-8, 10-13, 16-23, 25 and 26 are pending; claims 4, 6-8, 10-13, 16-23, 25 and 26 are withdrawn; claims 1-3 and 5 are under current examination.

#### ***Information Disclosure Statement***

Applicants' IDS, filed 12/20/05, has been considered.

#### ***Priority***

Acknowledgment is made of applicant's claim for priority based on PCT/EP2004/006474. It is noted, however, that applicant has not filed a certified copy of the PCT/EP2004/006474 application as required.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1-3 and 5) in the reply filed on 7/24/09 is acknowledged. The traversal is on the ground(s) that the restriction requirement be modified to include SEQ ID NO: 4 in the elected restriction group because SEQ ID NO: 4 represents a polynucleotide sequence that encodes the polypeptide sequence represented by SEQ ID NO: 10. Applicants argue that a single search for a polynucleotide encoding SEQ ID NO: 10 would identify any relevant art, as they relate to a polynucleotide including SEQ ID NO: 4, and would not constitute an undue burden on the Examiner.

This is found persuasive with respect to modification of the elected restriction group to include SEQ ID NO: 10 (part a) of claim 1. Thus, the elected group will include SEQ ID NO: 4, and the polypeptide encoded by SEQ ID NO: 4, SEQ ID NO: 10.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 4, 6-8, 10-13, 16-23, 25 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/24/09.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

An isolated polynucleotide sequence encoding an RC kinase polypeptide, wherein the polynucleotide encodes an amino acid sequence consisting of SEQ ID NO: 10 or a polynucleotide consisting of SEQ ID NO: 4.

Expression vectors and host cells comprising said polynucleotide and method for producing an RC kinase polypeptide wherein the method comprises a) culturing the host cells under conditions suitable for the expression of the RC kinase polypeptide and b) recovering the RC kinase polypeptide from the host cell culture.

The specification does not reasonably provide enablement for the breadth of the claims which encompass

- 1) amino acid sequences that are at least about 70% identical to the amino acid sequence shown in SEQ ID NO: 4,
- 2) polynucleotides which hybridize under stringent conditions to a polynucleotide in a) or b) of claim 1;

3) polynucleotides that represent fragments, derivatives, or allelic variants of said polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

*Nature of the Invention.* The claims are directed to an isolated polynucleotide encoding a RC Kinase polypeptide and being selected from the group consisting of:

a) a polynucleotide encoding a RC kinase polypeptide comprising an amino acid sequence selected from the group consisting of: amino acid sequences which are at least about 75% identical to the amino acid sequence shown in SEQ ID NO: 10 and the amino acid sequence shown in SEQ ID NO: 10;

b) a polynucleotide comprising the sequence of SEQ ID NO: 4;

c) a polynucleotide which hybridizes under stringent conditions to a polynucleotide specified in a) and b);

and e) a polynucleotide which represents a fragment, derivative or allelic variant of the polynucleotide sequence specified in a) to d). Further embodiments are directed to an expression vector containing the polynucleotide, host cells, and a method for producing an RC Kinase polypeptide by culturing the host cell.

*Breadth of the claims.* The breadth of the claims are so broad as to encompass 1) any nucleic acid encoding a variant, fragment or derivative of the polypeptide of SEQ ID NO: 10 having RC kinase activity wherein said variant or derivative has i) any amino acid sequence or ii) an amino acid sequence which is at

least 75% identical to SEQ ID NO: 10; or iii) is encoded by a nucleic acid which hybridizes under nonspecifically claimed stringent conditions to the polynucleotide of SEQ ID NO: 4 or to the polynucleotide encoding the polypeptide encoded by SEQ ID NO: 10; 2) any nucleic acid sequence encoding a polypeptide of any function wherein said polypeptide comprises a fragment of a protein having RC kinase activity, wherein said protein has an amino acid sequence 75% identical to the amino acid sequence of SEQ ID NO: 10; 3) vectors comprising the nucleic acids of 1) and 2); 4) methods to recombinantly produce the proteins encoded by the nucleic acids of 1)-2).

*Guidance of the Specification/The Existence of Working Examples.* The instant specification teaches that RC kinase is overexpressed in COPD patients (p. 1, lines 5-6). In particular, the specification teaches various upregulated genes in lung tissue from COPD patients, determined by microarray analysis (Figure 1). The specification teaches that the activity of the novel, human RC kinase contains a single serine-threonine catalytic domain, and the kinase domain is highly homologous to the kinase domains of other known kinase type enzymes. In particular that the human kinase shown in SEQ ID NO: 7, 8, 10 or 12 is 44% identical and 67% similar over 287 amino acids to the slime mold protein annotated as MEK kinase and 47% identical and 67% similar to a STE11 protein kinase homolog NPK1 and is 46% identical and 64% similar of 291 amino acids to the human protein identified as MAPKKK3. See page 8, lines 22+. The specification teaches that SEQ ID NO: 4 describes a splice variant which uses all exons except exon E (p. 9, lines 8-10). The specification teaches that RC kinase has the ability to phosphorylate the MAP kinase kinase MKK4, and to a lesser extent, MKK6, indicating that RC kinase is an activator in one or more MAP kinase signaling cascades (p. 51, lines 8+). The specification teaches that RC kinase appears to be upregulated and possibly activated by cellular stress, then phosphorylates MKK4 (and to a lesser extent MKK6) which leads to the activation of transcription factors

AP-1 and NF $\kappa$ b. See p. 51, lines 23+. The working examples in the specification teaches the transfection of RC kinase vectors into HEK293 cells, and shows that the RC kinase can phosphorylate other RC kinase polypeptides, MKK4 and MKK6 (Example 1). The specification teaches that RC kinase gene transcript was found to be expressed high in COPD patients than in normal lung (Example 6). The specification teaches the expression of RC kinase in various tissues, including lung, prostate, spinal chord, testis, trachea and uterus (Figure 4 and Example 7) and the cloning of the RC Kinase cDNA (Example 8). The specification teaches that the expression of RC kinase in cell lines HEK293, Jurkat and Daudi increased significantly after treatment of the cells with potassium chloride, which subjects the cells to hyperosmotic stress, and that this suggests that the higher expression of RC kinase in the lungs of COPD patients may be the result of cellular stresses caused by the irritants in tobacco smoke (Example 9); the specification teaches that the transfection and overexpression of RC kinase lead to the activation of the transcription factors AP-1 and NF $\kappa$ b and that overexpression of RC kinase causes a nearly 35-fold increase in the production of Interleukin 8 (Examples 10-11 and Figure 10).

The specification provides guidance for the splice variant, SEQ ID NO: 4. However, the specification fails to provide specific guidance as to the structural elements in the polypeptide encoded by SEQ ID NO: 10 which are essential for any protein to display RC Kinase polypeptide activity, or which structural elements in the polynucleotide of SEQ ID NO: 4 which are required in any nucleic acid such that it would encode a protein with RC kinase activity. The only guidance provided by the specification is that the RC kinase has a kinase domain that is highly homologous to the kinase domains of other known kinase type enzymes and that phosphorylate the MAP kinase kinase MKK4, and to a lesser extent, MKK6. However, there is no specific guidance provided by the specification as to which amino acids of the polypeptide of SEQ ID NO: 10 can be modified, and which ones

would be conserved in order to create a variant or derivative that displays the same activity as the polypeptide encoded by SEQ ID NO: 10.

*State of the Art/Predictability of the Art.* The nucleotide sequence of the coding region of a polynucleotide encoding a protein determines the structural and functional properties of that protein. In the instant case, neither the specification nor the art provide a correlation between structure and activity such that one of skill in the art can envision the structure of any nucleic acid encoding a polypeptide having the same biological function as that of the polypeptide of SEQ ID NO: 10. In addition, the art does not provide any teaching or guidance as to (1) which nucleotides in the polynucleotide of SEQ ID NO: 4 can be modified and which ones are conserved such that one of skill in the art can make variants as recited encoding polypeptides with the same biological activity as that of the polypeptide of SEQ ID NO: 10, (2) which segments of the polypeptide of SEQ ID NO: 10, or the polynucleotide of SEQ ID NO: 4, are essential for activity, other than the conserved kinase domain, and (3) the general tolerance of RC kinases to structural modifications and the extent of such tolerance. The art clearly teaches that changes in a protein's amino acid sequence to obtain the desired activity without any guidance/knowledge as to which amino acids in a protein are required for that activity is highly unpredictable. At the time of the invention there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity.

For example, the conservative replacement of a single lysine residue at position 118 of acidic fibroblastic growth factor by a glutamic acid, led to the substantial loss of heparin binding, receptor binding and the biological activity of the protein (see Burgess *et al.*, *J. of Cell Bio.*, 111: 2129-2138 (1990)). In transforming growth factor alpha, the replacement of aspartic acid at position 47 with alanine or asparagines did not affect the biological activity, however, the replacement of serine or glutamic acid sharply reduced the biological activity of the

mitogen (see Lazar *et al.*, *Mol. & Cell. Bio.*, 8: 1247-1252 (1998)). Thus, these references demonstrate that even a single amino acid substitution, or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity and characteristic of a protein. While it is known that many amino acid substitutions are possible, in any given protein, the position within the protein's sequence, where such an amino acid substitution(s) can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can only tolerate conservative substitutions, or no substitutions at all. Residues that are directly involved in protein functions, such as binding, will certainly be among the most conserved. There is no specific guidance provided by the specification with regard to the particular domains that are essential to the function of the RC kinase polypeptide. Therefore, reasonable correlation must exist between the scope of the claims and scope of enablement set forth and it cannot be predicted from the disclosure how to make and use the nucleic acid(s) that encode peptide variants of the RC kinase polypeptide.

*The Amount of Experimentation Necessary.* While methods of generating or isolating variants of a polynucleotide were known in the art at the time of the invention, it was not routine in the art to screen by a trial and error process for all polynucleotides encoding polypeptides having RC kinase activity. In the absence of (1) a rational and predictable scheme for modifying any nucleotide in the nucleic acid of SEQ ID NO: 10 such that the resulting variant would encode a protein which retains the RC kinase activity, and/or (2) a correlation between structure and RC kinase activity, one of skill in the art would have to test an essentially infinite number of polynucleotides to determine which ones encode proteins having RC kinase activity. Since the claims also encompass nucleic acids encoding proteins of any kinase function, it would also require undue experimentation to determine the

actual function of those nucleic acids such that the skilled artisan would know how to use them.

While enzymatic assays are well known in the art, and the skilled artisan can produce variants of the polynucleotide of SEQ ID NO: 10 or the polypeptide of SEQ ID NO: 4 having the recited structural characteristics using well-known and widely used techniques in the art, the amount of experimentation required is not routine due to the fact that the number of species encompassed by the claims is extremely large. Therefore, while enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, as is the case herein, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that a reasonable number of species can be selected for testing. In view of the fact that such guidance has not been provided in the instant specification, it would require undue experimentation to enable the full scope of the claims.

Therefore, taking into consideration the extremely broad scope of the claims, the lack of guidance, the amount of information provided, the lack of knowledge about a correlation between structure and function, the high degree of unpredictability of the prior art in regard to structural changes and their effect on function, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to practice the claimed invention. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

### ***Written Description***

Claims 1-3 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Vas-Cath Inc. v. Mahurkar* 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that, “[A]pplicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not, “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” *Vas-cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The claims encompass fragments, derivatives or variants of the polynucleotide that encodes for an RC kinase polypeptide. However, the specification fails to describe the entire genus of polynucleotides (*i.e.*, fragments, or derivatives or variants of SEQ ID NO: 4 or a fragement of a polypeptide encoded by SEQ ID NO: 10) when constructed and used as claimed, lacks a written description, and as such, there is no indication that Applicants had possession of the claimed invention. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification, and are not conventional in the art **as of Applicants’ effective filing date**. Possession may be shown by actual reduction to practice, clear depiction of the claimed invention in a detailed drawing, or by describing the invention with sufficient, relevant, identifying characteristics (as it relates to the claimed invention as a whole), such that one of skill in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). In the instant case, the breath of the genus of polynucleotides having a homology of 75% or more with SEQ ID NO: 10 and encoding a RC kinase polypeptide, or a polynucleotide encoding a RC kinase, which hybridizes to SEQ ID NO: 4, lacks a written description. From the specification, it is clear that Applicants had possession of a nucleic acid molecule encoding the RC kinase (SEQ

ID NO: 4), but fails to teach any other polynucleotides which lack the nucleic acid sequence of SEQ ID NO: 4 (or the polypeptide sequence SEQ ID NO: 10) and have the activity of an RC kinase polypeptide. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. There is not even identification of any particular portion of the structure that must be conserved. The specification does not provide a complete structure of those polypeptides that are fragments, derivatives and variants of the RC kinase encoded by SEQ ID NO: 4, or a polypeptide encoded by SEQ ID NO: 10 and fails to provide a representative number of species for the encompassed genus such that one of skill could readily identify polynucleotides having an identify of 75% or more with SEQ ID NO: 10 and have RC kinase activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the recited genus.

The claims encompass an extremely large genus of nucleic acids which are structurally or functionally unrelated. A sufficient written description of a genus of nucleic acids may be achieved by a recitation of a representative number of nucleic acids defined by their nucleotide sequence or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. However, in the instant case, either (1) there is no structural feature which is representative of all the members of the genus of nucleic acids recited in the claims, or (2) the structural features recited/interpreted, such as “75% sequence identical to SEQ ID NO: 4”, “a polynucleotide hybridizing under stringent conditions to the polynucleotide of SEQ ID NO: 4”, do not constitute a substantial portion of the genus as the remainder of any nucleic acid encoding/comprising said

structural elements is completely undefined and the specification does not define the remaining structural features for members of the genus to be selected. Absent factual evidence, a nucleic acid having a percentage sequence similarity of less than 100% would not be deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of a similar, known biomolecule. It known for nucleic acids, as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Even in polypeptide families, individual members can have distinct, and even opposite biological activities.

The skilled artisan cannot envision the detailed chemical structure of all of the polynucleotide fragments with 75% or more homology to SEQ ID NO: 110 and having the function of a RC Kinase, that are encompassed by the claims, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention, and a reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

While one could argue that SEQ ID NO: 4 is representative of all the members of the genus of nucleic acids claimed, or that the polypeptide of SEQ ID NO: 10 is representative of all the members of the genus of proteins encoded by the genus of nucleic acids claimed, such that the recited genus is adequately described by the disclosure of the structure of the polynucleotide of SEQ ID NO: 4, or the polypeptide of SEQ ID NO: 10, it is noted that the art teaches several examples of how even small changes in structure can lead to changes in function. For example, Witkowski et al. (Biochemistry 38:11643-11650, 1999, IDS) teaches that one

conservative amino acid substitution transforms a  $\beta$ -ketoacyl synthase into a malonyl decarboxylase and completely eliminates  $\beta$ -ketoacyl synthase activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) teaches that two naturally occurring *Pseudomonas* enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Therefore, since minor structural changes may result in changes affecting function, and no additional information correlating structure with claimed activity has been provided, one cannot reasonably conclude that the structures disclosed are representative of all nucleic acids encoding a RC kinase or nucleic acids encoding proteins of any function as claimed.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification only provided the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description of 35 U.S.C. 112 is severable from its enablement provision [see p. 1115].

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "at least about". The metes and bounds of this phrase cannot be determined. The term "at least about" in claim 1 is a relative term which renders the claim indefinite. The term "at least about" is not defined by

the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2, 3 and 5 are dependent on claim 1.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/090525 A2 (published November 14, 2002).

Regarding claim 1, the '525 document teaches SEQ ID NO: 2, which encodes a polynucleotide that is 88.2% identical to SEQ ID NO: 10 (see attached alignment) and is 76.4% identical to SEQ ID NO: 4 (see attached alignment). The '525 document teaches that these amino acid sequences encode human kinase peptides and proteins that are related to the MEK kinase alpha subfamily (see p. 5, lines 21-24). The '525 document teaches that these peptides can also include allelic variants and other variants (p. 7, lines 18-25; p. 10, lines 6-12) as well as fragments (p. 4, lines 6-16). The '525 document teaches that the nucleic acid molecules can encode fragments, derivatives and allelic variants of the kinase peptides, and can additionally include conservative amino acid substitutions (p. 28, lines 18-27). The '525 document teaches nucleic acids that can hybridize to the polynucleotides (p. 29, lines 13+).

Regarding claim 2, the '525 document teaches that the nucleic acids encoding the kinase peptides can be isolated (p. 26, lines 10+) and can be contained in an expression vector (p. 26, lines 25-26; p. 30, lines 19-24).

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Regarding claim 3, the '525 document teaches that the nucleic acids encoding the kinase peptides can be maintained in a host cell (p. 26, lines 26-27; p. 31, lines 3-4).

Regarding claim 5, the '525 document teaches that the isolated kinase peptides can be purified from cells that have been altered to express it recombinantly (p. 8, lines 17-18).

Accordingly, the '525 document anticipates the claims.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thaian N. Ton/  
Primary Examiner, Art Unit 1632